

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PURDUE PHARMA PRODUCTS L.P., NAPP  
PHARMACEUTICAL GROUP LTD., BIOVAIL  
LABORATORIES INTERNATIONAL SRL, and  
ORTHO-MCNEIL, INC.,  
  
Plaintiffs,  
  
v.  
  
PAR PHARMACEUTICAL, INC. and PAR  
PHARMACEUTICAL COMPANIES, INC.,  
  
Defendants.

## ANSWER AND COUNTERCLAIMS

Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, “Par”), by their attorneys, respond to the averments made in the numbered paragraphs of the complaint filed by plaintiffs Purdue Pharma Products L.P., Napp Pharmaceuticals Group Ltd., Biovail Laboratories International, SRL, and Ortho-McNeil, Inc. (collectively “plaintiffs”) as follows:

### NATURE OF THE ACTION

1. With respect to paragraph 1, Par admits that this is an action for patent infringement but denies that any violation of the patent laws has occurred.

## JURISDICTION AND VENUE

2. With respect to paragraph 2, Par admits that this Court has subject matter jurisdiction pursuant to the patent laws of the United States.

3. With respect to paragraph 3, Par admits that venue is proper in this Judicial District.

**THE PARTIES**

4. With respect to paragraph 4, Par admits that Purdue Pharma L.P. has a place of business at 201 Tresser Boulevard, Stamford, Connecticut 06901 and that the assignment records at the United States Patent and Trademark Office show that the patent in suit was assigned to Purdue Pharma Products L.P. Par is without sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 4, and therefore denies them.

5. With respect to paragraph 5, Par admits that Napp Pharmaceutical Group Ltd. has a place of business in the United Kingdom at 191 Cambridge Science Park, Milton Road, Cambridge, CB4 0GW and that the assignment records at the United States Patent and Trademark Office show that the patent in suit was assigned to Napp Pharmaceutical Group Limited. Par is without sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 5, and therefore denies them.

6. With respect to paragraph 6, Par admits that Biovail Laboratories Incorporated has a place of business in Carolina, Puerto Rico and that the FDA's Orange Book shows that Biovail Laboratories International is the holder of NDA No. 21-692 for extended release tramadol hydrochloride oral tablets. Par is without sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 6, and therefore denies them.

7. With respect to paragraph 7, Par admits that Ortho-McNeil has a place of business at 1000 U.S. Highway 202, Raritan, New Jersey 08869. Par is without sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegation in paragraph 7, and therefore denies them.

8. Par admits the allegations in paragraph 8.

9. Par admits the allegations in paragraph 9.

**THE PATENT IN SUIT**

10. With respect to paragraph 10, Par admits that U.S. Patent No. 6,254,887 was issued on July 3, 2001 and names Ronald Brown Miller, Stuart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo Hahn, and Derek Allan Prater as inventors. Par is without sufficient knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 10, and therefore denies them.

**PAR'S ANDA**

11. Par admits the allegations in paragraph 11.

12. Par admits the allegations in paragraph 12.

13. Par admits the allegations in paragraph 13.

14. Par admits the allegations in paragraph 14.

15. Par admits that on May 21, 2007 it sent a Notice of Paragraph IV Certification Letter to a) Biovail Laboratories International SRL in Barbados, West Indies and Washington, D.C. and b) to Napp Pharmaceutical Group, Ltd. in Cambridge, United Kingdom and c) to Purdue Pharma Products L.P. in Stamford, Connecticut. Par denies the remaining allegations of paragraph 15.

16. Par admits that on May 21, 2007 it sent a Notice of Paragraph IV Certification letter to a) Biovail Laboratories International SRL in Barbados, West Indies and Washington, D.C. and b) to Napp Pharmaceutical Group, Ltd. in Cambridge, United Kingdom and c) to Purdue Pharma Products L.P. in Stamford, Connecticut. Par denies the remaining allegations of paragraph 16.

17. Par denies the allegations in paragraph 17.
18. Par denies the allegations in paragraph 18.
19. Par denies the allegations in paragraph 19.
20. Par denies the allegations in paragraph 20.
21. Par denies the allegations in paragraph 21.
22. Par denies the allegations in paragraph 22.
23. Par denies the allegations in paragraph 23.
24. Par denies the allegations in paragraph 24.
25. Par denies the allegations in paragraph 25.
26. Par denies the allegations in paragraph 26.
27. Par denies each allegation not specifically admitted or otherwise responded to herein.

Par denies that plaintiffs are entitled to any of the relief requested in §§ A-E of plaintiffs' prayer for judgment.

#### **AFFIRMATIVE DEFENSES**

Without any admission to the burden of proof or as to any of the averments in the Complaint, Par sets forth the following affirmative defenses:

1. The '887 patent is invalid for failure to comply with one or more of 35 U.S.C. §§ 102, 103 and 112.
2. Par has not infringed any valid and enforceable claim of the '887 patent.

#### **COUNTERCLAIMS**

Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") assert the following claims against Purdue Pharma Products, L.P., Napp Pharmaceutical Group Ltd., Biovail Laboratories International SRL, and Ortho-McNeil, Inc. (collectively "plaintiffs"):

1. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. On information and belief, Purdue Pharma Products L.P. (“Purdue”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

4. On information and belief, Napp Pharmaceutical Group Ltd. (“Napp”) is a private limited company organized and existing under the laws of the United Kingdom, having a place of business at Cambridge Science Park, Milton Road, Cambridge, CB4 0GW.

5. On information and belief, Biovail Laboratories International SRL (“Biovail”), is a corporation organized and existing under the laws of Barbados, having a place of business in Carolina, Puerto Rico.

6. On information and belief, Ortho-McNeil, Inc. (“Ortho-McNeil”) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 1000 U.S. Highway 202, Raritan, New Jersey 08869.

7. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief, i.e., a declaration that the patent-in-suit is not infringed and that it is invalid.

8. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. U.S. Patent No. 6,254,887 (“the ‘887 Patent”), entitled “Controlled Release Tramadol” issued on July 3, 2001.

10. The assignment records at the United States Patent and Trademark Office show that the ‘887 Patent was assigned to Napp Pharmaceutical Group Limited and Purdue Pharma Products L.P. on May 4, 2007.

11. The ‘887 Patent concerns extended release tramadol tablets.

12. Par Pharmaceutical, Inc. submitted Abbreviated New Drug Application (“ANDA”) No. 78-783 to the Food and Drug Administration (“FDA”) seeking approval to market tramadol hydrochloride extended release tablets.

**FIRST COUNT**  
**(Declaration of Noninfringement)**

13. Par repeats and realleges paragraphs 1 through 12 of the counterclaim.

14. The ‘887 Patent claims do not cover Par’s proposed extended release tramadol tablets. Therefore, Par has not infringed, does not infringe, and would not infringe the ‘887 Patent if it made, used, sold, offered for sale, marketed, or imported its proposed product.

15. Plaintiffs have asserted the ‘887 Patent against Par. Plaintiffs maintain -- and Par denies -- that the ‘887 Patent claims cover Par’s proposed extended release tramadol tablets.

16. There is an actual, substantial, and continuing justifiable controversy between Par and plaintiffs regarding the infringement of the ‘887 Patent.

17. Par is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of its proposed extended release tramadol tablets has not infringed, does not infringe, and would not infringe the ‘887 Patent.

**SECOND COUNT**  
**(Declaration of Invalidity)**

18. Par repeats and realleges paragraphs 1 through 12 of the counterclaim.

19. The '887 Patent and all its claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

20. Plaintiffs maintain -- and Par denies -- that the '887 Patent claims are valid.

21. There is an actual, substantial, and continuing justiciable controversy between Par and plaintiffs regarding the validity of the '887 Patent claims.

22. Par is entitled to a judicial declaration that the '887 Patent claims are invalid.

**Prayer for Relief**

WHEREFORE, Par requests judgment in its favor and against the plaintiffs as follows:

(a) Dismissing the Complaint with prejudice and denying each request for relief made by plaintiffs;

(b) Declaring the '887 Patent is not infringed by the filing of Par's ANDA;

(c) Declaring the '887 Patent is not infringed by any making, use, sale, offer for sale, marketing, or importation of Par's proposed extended release tramadol tablets;

(d) Declaring the '887 Patent and all its claims invalid;

(e) Enjoining the plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any plaintiff from threatening to assert or otherwise attempting to enforce the '887 Patent against Par, its customers, suppliers, or anyone in privity with Par.

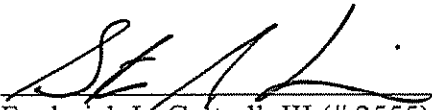
(f) Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding Par its attorneys' fees;

(g) Awarding Par its costs and expenses; and

(h) Awarding Par such other and further relief as the Court deems just and proper.

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Dated: July 23, 2007



**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I hereby certify that on July 23, 2007, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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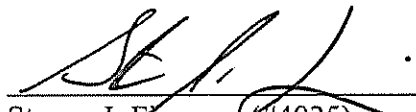
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I hereby certify that on July 23, 2007, I have sent by Federal Express, the foregoing document to the following non-registered participants:

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